

REMARKS

In reply to the Office Action dated June 18, 2004, claims 1, 3, 4, 8, 11, and 15 are currently under examination in the Application. By the above amendment, claims 8 and 15 have been canceled, claims 1, 3, and 11 have been amended, and new claim 18 has been added. Claims 3 and 11 have been amended solely to add dependence on claim 18. Support for amended claim 1 can be found throughout the specification as filed. Support for new claim 18 can be found throughout the specification as filed, for example, at page 28, lines 10-23. No new matter has been added. With the amendment, claims 1, 3, 4, 11, and 18 are pending. The above amendment is not to be construed as acquiescence to the stated grounds for objection/rejection and is made without prejudice to prosecution of any subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application.

Applicants wish to thank the Examiner for acknowledgment of the Information Disclosure Statements filed April 16, 2002 and March 26, 2003.

Claim Rejections – 35 U.S.C. § 112, first paragraph (written description)

Claims 1, 3, 4, 8, 11, and 15 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Applicants, at the time the application was filed, had possession of the claimed invention. In particular, the Action contends that the specification provides insufficient written description to support the genus encompassed by the claims. Further the Action alleges that the species specifically disclosed in the specification are not representative of the genus because the genus is highly variant.

Applicants traverse the rejection on the following grounds.

As an initial matter, Applicants submit that claim 1 has been amended without prejudice and solely to expedite prosecution. Applicants reserve the right to pursue any subject matter removed or modified by this amendment in a related divisional, continuation and/or continuation-in-part application. Amended claim 1 recites an isolated polynucleotide comprising a sequence selected from the group consisting of the sequence provided in SEQ ID NO:343; the

complement of the sequence provided in SEQ ID NO:343; and degenerate variants of the sequence provided in SEQ ID NO:343, wherein said variants encode the polypeptide encoded by SEQ ID NO:343. Accordingly, Applicants submit that the grounds for rejection have been obviated. Applicants address this rejection as it may potentially apply to the newly added claim 18.

Applicants submit that the U.S.P.T.O. has specifically indicated that possession of an invention is more readily established, and correspondingly greater claim breadth is permissible, where an Applicant discloses functional and/or descriptive information concerning the specie(s) in an application, *e.g.*, a distinguishing identifying characteristic common among the members of a claimed genus (see *Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, "Written Description" Requirement* – Federal Register: January 5, 2001 (Volume 66, No. 4, pgs. 1099-1111). For example, at the bottom of pg. 1105, the *Guidelines* state that, “(a)n adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention.” The *Guidelines* go on to state at page 1106, first column that “What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail.”

First, Applicants submit that the specification clearly discloses the breast tumor expression of the B305D antigen (see in particular Example 1 and Example 7). Second, Applicants submit that the specification clearly discloses the detailed structure of the polynucleotide set forth in SEQ ID NO:343. In view of the breast and breast tumor-specific expression profile identified by Applicants for this sequence, the skilled artisan would undoubtedly understand and expect that a multitude of sequences structurally related to SEQ ID NO:343, *e.g.*, sequences having at least 90% identity to SEQ ID NO:343, would be diagnostically useful in the same capacity as the specific species of SEQ ID NO:343. More particularly, sequences having at least 90% identity with SEQ ID NO:343, based upon their structural similarity to, and thus specificity for, a sequence of SEQ ID NO:343, will hybridize, using assays known in the art and described in the specification, to a sequence of SEQ ID NO:343, and accordingly would be useful in detecting over-expression of SEQ ID NO:343 in a

biological sample in the same manner as one would use the precise sequence of SEQ ID NO:343 to detect overexpression of SEQ ID NO:343 in a biological sample. This understanding and expectation on the part of the skilled artisan is soundly based upon fundamental scientific principles of nucleic acid hybridization, namely that a sequence having at least 90% identity to a sequence of SEQ ID NO:343 will indeed hybridize to the sequence of SEQ ID NO:343 and therefore will be useful in detecting cancers associated with over-expression of SEQ ID NO:343, despite the fact that the sequences are not identical to SEQ ID NO:343.

Accordingly, Applicants disagree with the contention that they were only in possession of the specific sequence of SEQ ID NO:343 at the time this application was filed. Applicants submit that to accept such a position would result in the exclusion of an entire class of sequences related to SEQ ID NO:343 that are useful in the context of the Applicants' invention, despite the fact that the skilled artisan would absolutely recognize the value of sequences related to SEQ ID NO:343 in the context of the Applicants' disclosure.

Moreover, by the present amendment, Applicants specifically incorporates the identifying characteristic into the claims under consideration, such that a polynucleotide of the invention is for use in the detection of breast cancer and can "hybridize to the polynucleotide of SEQ ID NO:343 under highly stringent conditions". Accordingly, in view of the Applicants' identifying characteristic disclosed for SEQ ID NO:343, applicants respectfully submit that the skilled artisan would appreciate that applicants were in clear possession of a genus of sequences related by % identity to SEQ ID NO:343 that would be similarly useful in a diagnostic context based upon their specificity for the sequence of SEQ ID NO:343. Applicants thus submit that the instant claims fully comply with the written description requirements of 35 U.S.C. § 112, first paragraph. Reconsideration of the Examiner's rejection is respectfully requested.

Claim Rejections – 35 U.S.C. § 112, second paragraph (indefiniteness)

Claims 1, 3, 4, 11, and 15 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter with applicant regards as the invention. In particular, the Action contends that claim 1, part (c) recites broad language followed by a narrow range or limitation that falls within the

broad range or limitation, thereby rendering it indefinite. Specifically, claim 1, part (c) recites the broad recitation "at least" while also reciting "consisting of" which is the narrower statement of the range/limitation. Further, the Action alleges that recitation of "degenerate variants" is indefinite without clarification that the variants encode the same polypeptide as that encoded by the recited SEQ ID NO:343.

Without acquiescing to the rejection, Applicants have amended claim 1 without prejudice to remove recitation of part (c) and to add the recitation "wherein said variants encode the polypeptide encoded by SEQ ID NO:343" as suggested by the Examiner. Accordingly, Applicants submit that the rejection has been obviated and may be properly withdrawn. Applicants reserve the right to pursue any subject matter removed or modified by this amendment in a related divisional, continuation and/or continuation-in-part application.

Claim Rejections – 35 U.S.C. §§ 102(b) and 102(e)

Claims 1, 3, 4, 8, 11, and 15 stand rejected as allegedly being anticipated under 35 U.S.C. § 102(b) over GenBank BF676987 (2000) or GenBank BF329652 (2000) or GenBank B48260 (1999) or WO 01/34802 or WO 01/51633 or WO 00/61753. Claims 1, 3, 4, 8, 11, and 15 stand rejected as allegedly being anticipated under 35 U.S.C. § 102(e) over Retter et al. (US 6,656,480) or Xu et al. (6,630,305) or Xu et al. (6,620,922) or Xu et al. (6,329,505) or Frudakis et al. (6,229,054 – PTO-1449) or Frudakis et al. (6,344,550). In particular, the Action contends that the references disclose sequences having at least 20 contiguous nucleotides of SEQ ID NO:343, sequences that would hybridize to SEQ ID NO:343 under highly stringent conditions, and sequences that have 89.2% identity to SEQ ID NO:343 (WO 01/34802 or WO 01/51633 or WO 00/61753 or, 6,656,480 or 6,630,305 or 6,620,922 or 6,329,505 or 6,229,054 or 6,344,550). Further, the Action contends that the references disclose a vector, host cell transformed with the vector, compositions comprising carriers, and immunostimulants. Accordingly, the Action concludes that the claims are anticipated by the cited references.

Applicants submit that the rejection has been rendered moot in view of the amended claims. Applicants note that the amendments are made without acquiescing to the

above rejection and solely to expedite prosecution. Applicants submit that the amended claims are not anticipated by the cited art and respectfully request withdrawal of the rejection.

Double Patenting

Claims 1, 3, 4, 8, 11, and 15 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1 and 7-9 of U.S. Patent No. 6,344,550. In particular, the Action contends that the sequences recited in the '550 claims have 87.9% identity to the claimed sequence of SEQ ID NO:343, have at least 20 contiguous nucleotides of SEQ ID NO:343, and would hybridize to the SEQ ID NO:343. Accordingly, the Action concludes that the conflicting claims are not patentably distinct from the present claims.

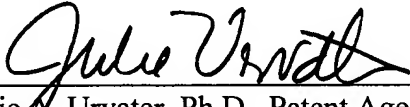
Applicants submit that the rejection has been rendered moot in view of the amended claims. Applicants note that the amendments are made without acquiescing to the above rejection and solely to expedite prosecution. Applicants submit that the amended claims are not anticipated by the cited art and respectfully request withdrawal of the rejection.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that all the claims remaining in the application are now believed allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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